

Atty's Docket:101195-54
DORKEN et al.,

Indefiniteness

Claims 1 and 8 are rejected under § 112, 2nd paragraph as being indefinite.

In brief, these claims have been amended to delete the offending terminology and to more clearly state the claimed subject matter.

Claim 1 now simply states that the transgene is located between the two multicloning sites.

Claim 8 now indicates that each multicloning site has between about 5 to 10 sites for restriction enzyme cutting sites.

Applicants respectfully request that this rejection be withdrawn.

Written Description Rejection

Claims 1-3, and 6-10 were rejected as lacking an adequate written description. Examiner believes that there is written description regarding the chemical structure of YB-1 promoter deletion mutants.

Applicants respectfully disagree. There is clear disclosure for the intact YB-1 promoter as disclosed by its GenBank accession number. Further, Applicants specifically disclose a deletion variant having nucleotides 453-2150 of the GenBank sequence. It is respectfully submitted that this recitation of the specific nucleotide positions comprising less than the entire promoter constitutes a deletion mutant or variant.

Persons of ordinary skill would have no problem understanding the Applicants' promoters, and appreciating Applicants' possession of the same.

In addition, Applicants' respectfully disclose the relationship between the promoter, the transgene cloned into a multiple cloning site, and the specific nucleotides of the multiple cloning site. See bottom page 5, to top page 6. A graphic depiction is generally represented in Figures 2 and 3. Thus, in contrast to Examiner's assertions, the relationship among promoter, transgene and MCS are disclosed.

In view of these remarks, Applicants respectfully solicit withdrawal of the written description rejections.

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Anticipation Under § 102(b)

Claims 1-3 and 6 have been rejected because Examiner apparently believes that Makino anticipates these claims.

Applicants respectfully point out that there is no disclosure of an expression plasmid having two multicloning sites. Accordingly, Makino does not encompass each claim limitation and cannot anticipate the claims.

It is respectfully requested that the anticipation rejection be withdrawn.

Obviousness

Claims 1, and 7-10 are rejected as allegedly being obvious over Makino in view of Araki and Gorman, and further in view of the Pharmacia Biotech Catalog. In essence, Examiner states that Makino and Gorman teach or suggest the claimed vector, and that the Pharmacia reference further teaches or suggests the use of multicloning sites.

Applicants respectfully point out that the claimed vector encompasses two multicloning sites that flank a transgene. There is not a single reference that discloses or suggests the desirability of this arrangement.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983). Thus, Examiner cannot simply overlook that Makino and Gorman do not disclose the use of one or more MCS.

Further, on pages 121-126 of the Pharmacia Catalog, it is clear that should an enhanced multicloning capability be required, Pharmacia shows an indisputable preference for simply increasing the size and complexity of a single multicloning site.

In view of Pharmacia having substantially more than mere ordinary skill in the art, their reliance on a single MCS is tantamount to a clear teaching away from two or more MCS sites. In fact, when taken in view of Makino and Gorman not disclosing any MCS, Pharmacia also teaches away from the combination of references.

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It long settled that it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 218 USPQ 769, 779 (Fed. Cir. 1983).

In addition, "[a] reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 31 USPQ2d 1130 (Fed. Cir. 1994). In other words, references that disclose using one MCS or none at all would have discouraged the ordinary skilled artisan from taking a research path requiring two flanking MCS sites.

Therefore, Applicants respectfully suggest that the applied combination of references cannot render the claimed vector obvious because they fail to either teach or suggest an important claim limitation.

Accordingly, Applicants respectfully request the withdrawal of the prior art rejections, and all rejections under § 112.

Respectfully Submitted,

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